UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITEDHEALTHCARE INSURANCE COMPANY AND UNITED HEALTHCARE SERVICES, INC., Plaintiffs, vs. REGENERON PHARMACEUTICALS, INC., Defendant.	**Case No. 7:20-cv-10664** **COMPLAINT** **DEMAND FOR JURY TRIAL**

UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "United") bring this Complaint against Regeneron Pharmaceuticals, Inc. ("Regeneron"), and further allege as follows.

NATURE OF THE ACTION

1. Eylea is a macular degeneration drug manufactured by Regeneron that costs $1,850 per dose. There is an equally effective competing drug that costs only $55 per dose—roughly 3% of Eylea's price. Yet Eylea is the top-selling drug of its kind in the United States, generating billions of dollars in revenue for Regeneron annually. Regeneron has achieved this unlikely result by breaking the law, concealing its actions, and deceiving insurers like United.

2. Since 2013, Regeneron has engaged in an illegal scheme designed to inflate the price of Eylea. Regeneron secretly coordinated with a purportedly independent charity, the Chronic Disease Foundation ("CDF"), to tailor the amount of its donations to CDF to only the amount necessary to offset cost-sharing obligations of Eylea patients, while eliminating the possibility that Regeneron's donations could be used to benefit patients using any other manufacturer's competing drugs.

3. Regeneron made these covert, targeted payments to CDF to ensure that patients could obtain Eylea at no cost, rendering it "cheaper" to patients than competing drugs, and eliminating any sensitivity to the drug's true price among patients and their physicians. Based on this scheme, Regeneron set Eylea's price well beyond what the market would otherwise bear, and left third parties—including Medicare Part C plan sponsors like United—to foot the large majority of the inflated bill.

4. Regeneron concealed its scheme to inflate Eylea's price for years. But an investigation by the Department of Justice recently dragged Regeneron's scheme into the light.

5. Documents unearthed by the Department of Justice show that, in 2012, Regeneron hired consultants to advise it in pricing Eylea. The consultants explained that paying patients' cost-sharing obligations by funneling the payments through a third-party charity would allow Regeneron to charge significantly higher prices for Eylea.

6. Regeneron did just that. Beginning in late 2012, Regeneron sought information from the CDF regarding how much it needed to "donate" to eliminate the cost-sharing obligations of Eylea patients insured through Medicare—to the exclusion of patients using competing drugs. The CDF effectively invoiced Regeneron for specific dollar amounts calculated to cover Eylea patients' cost-sharing obligations, and Regeneron made corresponding donations. The CDF then applied these amounts to cover the cost-sharing obligations of patients using Eylea, with the understanding that there would be a one-to-one correlation between what Regeneron donated and what the CDF paid out for Eylea. This rendered Eylea "free" to patients, while leaving their insurers to pay the balance of the drug's inflated cost.

7. Then, in collaboration with a consulting firm called the Lash Group, Regeneron created the EYLEA4U program. The program served two purposes. First, it advertised the

availability of purportedly "charitable" funding for Eylea through the CDF, deliberately using Regeneron's illegal kickback scheme to induce physicians to prescribe Eylea, and patients to use it. Second, the EYLEA4U program monitored and facilitated payments to physicians from insurers like United, whom Regeneron understood would ultimately bear Eylea's cost.

8. The scheme worked precisely as planned. Regeneron set an inflated price near the top of the range recommended by its consultants in 2012, secure in the knowledge that the cost would not deter physicians or patients from utilizing Eylea in favor of cheaper alternatives. Regeneron then reaped windfall profits over the course of years. In 2019 alone, Regeneron brought in *$4.6 billion* from sales of Eylea.

9. These profits came at the expense of taxpayers and insurers like United. As a direct result of Regeneron's scheme, Medicare programs have spent $11.5 billion to cover the cost of Eylea since 2013. United, as a Medicare Part C (or Medicare Advantage) Plan sponsor, bears the cost of Medicare spending for the beneficiaries enrolled in United's Medicare Advantage plans. United has paid out approximately $917 million for Eylea on behalf of Medicare beneficiaries enrolled in United plans, including approximately $73.7 million in 2013 and 2014 alone.

10. Regeneron's scheme was patently illegal. Among other things, it violated the False Claims Act, the Federal Anti-Kickback statute (42 U.S.C. § 1320a-7b), and various state laws that similarly prohibit pharmaceutical companies from covering their customers' cost-sharing obligations. Indeed, a number of pharmaceutical companies have paid the United States government hundreds of millions of dollars in recent years to settle claims arising out of materially identical conduct.

11. Because the claims submitted to United's Medicare plans for Eylea treatment were tainted by Regeneron's illegal kickback scheme, they were not payable under federal law.

Knowing this, Regeneron deliberately misrepresented and concealed the nature of its relationship with the CDF. Not only did Regeneron publicly claim not to play any role in the CDF's funding, but internal Regeneron emails show that Regeneron executives repeatedly lied to company auditors who might have blown the whistle on the company's illegal activities.

12. In addition to breaking the law, Regeneron's conduct also subverted key terms of United's contracts with its insureds. Under United's Medicare plans, members are required to share in the cost of prescription drugs through copayments or coinsurance. By paying kickbacks to induce the purchase of Eylea, Regeneron tortiously interfered with United's contracts with its members, causing United to pay for Eylea where members had not met their contractual cost-sharing obligations.

13. Regeneron's scheme harmed not only insurers but also the public at large. Indeed, one study showed that if patients used Avastin,[1] a drug that costs a fraction of what Eylea costs but has been found to be equally as safe and effective, Medicare and American Taxpayers could save $18 *billion* over 10 years.

14. Drug prices are higher in the United States than anywhere else in the world. For example, consumers in the United States pay three times more for the world's 20 top-selling drugs than do consumers in the United Kingdom. Cost-sharing is thus a cornerstone of the Medicare program, instituted by Congress in part as "a safeguard against inflated drug prices."[2] This promotes prudent consumption and spurs price competition in the pharmaceutical market.

[1] David Hutton, Paula Anne Newman-Casey, Mrinalini Tavag, David Zacks, and Joshua Stein, *Switching To Less Expensive Blindness Drug Could Save Medicare Part B $18 Billion Over A Ten-Year Period*, Health Affairs Vol. 33, NO. 6 (2014), https://tinyurl.com/y2a4pdek.
[2] Department of Justice, *Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks* (Dec. 6, 2018), https://tinyurl.com/y67zsuj9.

Regeneron deliberately undermined these goals with its scheme, to the ultimate detriment of insurers and insureds alike.

15. But now the curtain has been pulled back on Regeneron's deceptive scheme. The Department of Justice filed suit against Regeneron on June 24, 2020. With the filing of the government's complaint and its exhibits, undeniable evidence of Regeneron's scheme is now a matter of public record. The same violations of federal law that cost the federal government billions of dollars damaged United to the tune of tens, if not hundreds, of millions of dollars. Accordingly, United now brings suit to recover its damages and put a stop to Regeneron's unlawful scheme.

PARTIES

16. Plaintiff UnitedHealthcare Insurance Company is a corporation organized under the laws of the State of Connecticut, with its principal place of business in the State of Connecticut. UnitedHealthcare Insurance Company fully-insures and administers health plans, including Medicare Part C plans at issue in this litigation.

17. Plaintiff United Healthcare Services, Inc. is a corporation organized under the laws of the State of Minnesota, with its principal place of business in the State of Minnesota. United Healthcare Services, Inc. fully-insures and administers health plans, including Medicare Part C plans at issue in this litigation.

18. Defendant Regeneron Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York with its principal place of business in Tarrytown, NY. Regeneron's wrongful conduct was authorized, ordered, and/or undertaken by Regeneron's various officers, agents, employees, or other representatives while actively engaged in the management of Regeneron's affairs. That conduct was undertaken within the course of the employment of

Regeneron's officers, agents, employees, or other representatives, within the scope of their duties, and with their actual, apparent, or ostensible authority.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332 because there is complete diversity of citizenship between United and Regeneron and the amount in controversy exceeds $75,000.

20. This Court also has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because it arises under the Constitution, laws, or treaties of the United States. Specifically, United asserts claims arising under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1962, *et seq*. The Court likewise has subject matter jurisdiction over United's state and common law claims under 28 U.S.C. § 1367, as those claims are so related to the federal claims that they form part of the same case or controversy.

21. This Court has personal jurisdiction over Regeneron in this action because Regeneron is incorporated and headquartered in the State of New York.

22. Venue is proper in this district under 28 U.S.C. § 1391 because Regeneron resides in this district and a substantial part of the events giving rise to the claims in this action have occurred in this district. Specifically, Regeneron devised and directed its unlawful scheme in this district.

BACKGROUND ALLEGATIONS

Neovascular (Wet) Age-Related Macular Degeneration

23. This case concerns a drug used to treat a chronic eye condition called neovascular (or "wet") age-related macular degeneration.

24. Age-related macular degeneration ("AMD") is a leading cause of vision loss in the United States and around the world, particularly among people over the age of 50. As many as 11 million people in the United States suffer from AMD. The risk of AMD increases with age, with the condition effecting an estimated 14% of people in the United States over the age of 80.

25. There are two types of AMD. Most cases (approximately 90%) are nonexudative or "dry" AMD, which progresses slowly and manifests minimal symptoms in its early stages.

26. The second form of the condition, neovascular or "wet" AMD, accounts for fewer cases but causes far more severe symptoms. It occurs when a protein called vascular endothelial growth factor ("VEGF") prompts abnormal blood vessel growth in the back of the eye. The abnormal blood vessels bleed or leak fluid, which can cause blind spots and blurry vision. Wet AMD typically follows dry AMD, and frequently renders those suffering from it legally blind.

27. There are two forms of treatment for wet AMD. First, photodynamic therapy treats wet AMD by using a combination of lasers and a light-sensitive medicine called verteporfin to break down the abnormal blood vessels that cause wet AMD.

28. The more common form of treatment, however, is anti-VEGF injections. Anti-VEGF drugs impede the growth of blood vessels that cause wet AMD and reduce swelling. While anti-VEGF injections can slow vision loss caused by wet AMD, they do not cure the condition. Anti-VEGF drugs therefore require regular doses indefinitely.

Eylea and Competing Anti-VEGF Drugs

29. Eylea is an anti-VEGF drug manufactured by Regeneron. Regeneron obtained FDA approval for Eylea to treat wet AMD in 2011. It has since become Regeneron's most profitable drug, generating billions of dollars in annual sales.

30. Despite its success, Eylea is neither the most effective anti-VEGF drug, nor the least expensive.

31. Eylea costs $1,850 per dose. The recommended course of treatment requires an injection every four weeks for the first five doses, and another injection every eight weeks thereafter indefinitely. The annual cost of Eylea thus well exceeds $10,000.

32. Eylea's primary competitors are two drugs manufactured by Genentech, Inc.

33. The first competitor, Lucentis, is an anti-VEGF drug approved by the FDA to treat wet AMD, priced comparably to Eylea at $2,000 per dose.

34. The second competitor, Avastin, is chemically similar to Lucentis but with FDA approval only for use in treating certain forms of cancer. Clinical studies show, however, that it is comparably effective to both Eylea and Lucentis in treating wet AMD if used off-label for that purpose.[3]

35. The primary difference between Avastin and competing anti-VEGF drugs is that Avastin costs far less than Eylea and Lucentis. Compounding pharmacies purchase Avastin and sell it for off-label use as a treatment for wet AMD at approximately $55 per dose—roughly 3% of the cost of Eylea.

[3] National Eye Institute, *Avastin as Effective as Eylea for Treating Central Retinal Vein Occlusion* (May 9, 2017), https://tinyurl.com/y3y73bgf.

36. Despite the fact that Avastin provides the same benefits as Eylea at a small fraction of the cost, Eylea is presently the top-selling drug in the United States for treating wet AMD.

Benefit Design and Impact of Cost-Sharing Waivers

37. Health plan members play an essential role in managing healthcare costs because there are no formal legal constraints on drug prices in the United States.

38. One way payors address this issue is by including cost-sharing obligations and contingent coverage as part of their benefits design.

39. Cost-sharing obligations refer to a member's responsibility to pay out-of-pocket for some portion of the cost of coverage.

40. Cost-sharing obligations are intended to cause behavioral shifts in members' decisions regarding healthcare services. The intent of cost-sharing is to provide an incentive for members and their physicians to use lower-cost alternatives when possible. And if alternatives are not available, members' inability to pay cost-sharing obligations is intended to have downward pressure on the pricing of expensive drugs.

41. Unwilling to lower their prices, many drug manufacturers have attempted to work around the downward pricing pressure caused by member cost-sharing obligations by either waiving those cost-sharing obligations or by paying those cost-sharing obligations on behalf of the members. The result of these payments, which are effectively cost-sharing waivers, is that the member is not exposed to the cost of the drug, allowing manufacturers to maintain already high prices or inflate prices without having to worry about the impact of those prices on anything other than profit to the manufacturer.

42. The effect of cost-sharing waivers on drug prices is well studied. For example, a large study conducted in Germany in 1989 showed that when drug companies were prevented from

waiving cost-sharing obligations, drug prices dropped on average between 10 and 26 percent. In other words, the drug manufacturers were able to substantially inflate prices simply by waiving required patient responsibility.[4]

43. Researchers have also discussed the effect of drug-company sponsored patient assistance programs. Specifically in a 2009 article,[5] researchers noted:

> Drug company-sponsored PAPs [Patient Assistance Programs] may inhibit cost-effective medication use, and their widespread use may have important implications for public drug spending. This potential impact must be better understood. Drug company–sponsored PAPs may steer patients toward and lock them into a particular manufacturer's product, even when other equally effective and less costly alternatives are available. If these patients ultimately acquire better coverage, then they may request unnecessarily expensive medications. In the case of Medicare Part D, patients' prior use of PAPs that provide subsidies for brand-name products may lead to higher overall individual and public drug spending.

44. Similarly, a 2014 article in the New England Journal of Medicine[6] explained:

> Assistance programs are a triple boon for manufacturers. They increase demand, allow companies to charge higher prices, and provide public-relations benefits. Assistance programs are an especially attractive proposition for firms that sell particularly costly drugs. Faced with high out-of-pocket costs, some patients may decide against taking an expensive medication. Patient-assistance programs can convert such patients from nonusers to users. Programs must incur costs for patients who would have used the drug even in the absence of a program, but manufacturers can afford to pay a lot of $25 or $50 copayments in return for even a small increase in the sales of a $50,000 drug.

45. In other words, by paying patient cost-share obligations, drug manufacturers can remove the downward price pressures on their drugs that the patients in a non-distorted market would otherwise apply. Insurers like United must foot the bill of these inflated costs.

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[4] Nina Pavcnik, *Do Pharmaceutical Prices Respond to Potential Patient Out-of-Pocket Expenses?*, RAND Journal of Economics Vol. 33, No. 3 (Autumn 2002), https://tinyurl.com/y5nhjto3.

[5] Choudhry, Niteesh K *et al*., *Drug company-sponsored patient assistance programs: a viable safety net?,* Health Affairs (Project Hope), Vol. 28, No. 3 (2009), https://tinyurl.com/y33pp57k.

[6] David H. Howard, *Drug Companies' Patient-Assistance Programs—Helping Patients or Profits?*, New England Journal of Medicine (2014), https://tinyurl.com/y66kwwea.

United's Administration of Medicare Part C Plans

46. United is a health services company that provides health care insurance, administration, and/or benefits to insureds or plan participants pursuant to a variety of benefit plans and policies of insurance, including group and individual health benefit plans, employer-sponsored benefit plans, and government-sponsored benefit plans.

47. United aims to provide the individuals covered by the benefit plans it insures and administers with comprehensive healthcare coverage at affordable costs, from well-qualified medical professionals, at professionally staffed and accredited medical facilities.

48. In its capacity as an insurer and as a claims administrator, United processes millions of health care claims per day, and is responsible for administering hundreds of millions of health care claims every year.

49. While United offers and administers a variety of different plans, Regeneron's misconduct here specifically targeted United's Medicare Part C (or Medicare Advantage) plans, which United administers for Medicare beneficiaries.

50. The Medicare program has four "parts" through which health benefits are provided to eligible Americans. Medicare Part A covers inpatient hospital services, skilled nursing facility services, and some forms of home-based care. Medicare Part B covers physician services, outpatient hospital services, diagnostic services, and other medical services. Both Parts A and B cover drugs delivered during a medical procedure, but Part B also covers outpatient drugs and biologics that require clinical administration, *e.g.*, drugs like chemotherapies that require intravenous application and monitoring by medical staff. Parts A and B together are the "original" Medicare programs that the United States government directly administers through the Centers for Medicare and Medicaid Services ("CMS").

51. Patients who are eligible for Part A and already enrolled in Part B have the option of choosing Medicare Part C, also called Medicare Advantage. Medicare Advantage plans are plans that combine the benefits of the two original Medicare parts, and often include prescription drug coverage as well. Private health insurers known as Medicare Advantage Organizations ("MAOs") provide these plans under contract with CMS.

52. United provides Medicare Advantage plans both as standalone Part C offerings, or combination products that include Part C and Part D. United's Medicare Advantage plans can take the form of a health-maintenance organization or a preferred provider organization, both of which use different tools to incentivize the efficient use of medical care by beneficiaries.

53. Taxpayer dollars underwrite Medicare Advantage plans. For each enrollee, CMS pays MAOs a capitated (per-person) amount each month. It is the MAO's job to manage those funds to ensure that benefits are available to beneficiaries when they need them and to ensure that those dollars do not go to waste.

54. Generally, Medicare beneficiaries are required to pay for a portion of the cost of insurance themselves; under Medicare Advantage, such cost-sharing obligations can come in the form of premiums, deductibles, co-pays, or co-insurance. Plans vary as to how these tools are used in order to provide beneficiaries with different cost structures. For example, a plan with low monthly premiums may require patients to pay more in co-pays or co-insurance. Plans with high premiums generally have lower out-of-pocket costs for each medical visit. But one of the defining features of Medicare Advantage plans is that beneficiaries' out-of-pocket expenses are capped each year. Beneficiaries with original Medicare face unlimited out-of-pocket expenses.

55. Medicare Advantage plans are required to cover the services available to original Medicare beneficiaries. As relevant here, Medicare Part B will always pay for clinically

administered drugs like Eylea—drugs provided incident to a physician's treatment and at the physician's office—if the drug is used as approved by the Food and Drug Administration. For individuals who have chosen to enroll in a Medicare Advantage plan rather than traditional Medicare, Eylea is reimbursed under the medical benefit of Medicare Part C.

56. Claims are not payable under Medicare if they do not comply with all applicable federal laws. For example, compliance with the Anti-Kickback statute, discussed below, is a condition of payment under Medicare.

57. As a condition of participating in Medicare, providers must certify that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act))."

58. Providers submit claims for Medicare beneficiaries to United and other payors using a standard claim form, the CMS 1500. This form requires the provider to certify that each claim "complies with all Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute."

59. The details of the Medicare Advantage plans that United administers are set forth in a document titled "Evidence of Coverage." CMS mandates that insurers use approved language in their Medicare policy documents, including the Evidence of Coverage. CMS's approved language is publicly available and United adopts those materials as issued by CMS for its own Evidence of Coverage documents.

60. An example of a United Evidence of Coverage written for a United Medicare Advantage plan, the UnitedHealthcare MedicareComplete Choice (Regional PPO), which incorporates Medicare's model language, is attached hereto as Exhibit A.

61. United's obligation to pay for medical benefits generally begins once a patient satisfies their annual deductible. Some United plans have no deductible, and therefore United's coverage begins immediately upon a beneficiary's enrollment in a given year. United beneficiaries then are responsible for paying for a portion of their medical care until they hit their out-of-pocket maximum.

62. A beneficiary's responsibility for clinically administered drugs like Eylea typically takes the form of coinsurance—the beneficiary pays a percentage of charges. For example, the UnitedHealthcare MedicareComplete Choice Evidence of Coverage requires beneficiaries to pay 20% of the drug's price. Ex. A at 4-23. This requirement applies until the patient hits their maximum out-of-pocket for the plan year. *Id*.

63. The UnitedHealthcare MedicareComplete Choice Evidence of Coverage contains a Medical Benefits Chart that describes what services are covered under the plan, and what a beneficiary is expected to pay during the coverage phase. *See generally*, Ex. A, Chapter 4. The Benefits Chart clearly lays out that in connection with each benefit described, the beneficiary *must* pay the cost share amounts listed in the chart. For Medicare Part B Prescription Drugs—those such as Eylea—beneficiaries must pay 20% of the drug's cost when received from an in-network provider, or 30% for an out-of-network provider. Ex. A at 4-23.

Legal Prohibitions on Pharmaceutical Companies Paying Patient Cost-Sharing

64. Federal and state law prohibit pharmaceutical companies from paying the cost-sharing obligations of their customers.

65. Medicare Part C is a "Federal health care program" as defined by 42 U.S.C. § 1320-7b(f), and therefore pharmaceutical companies like Regeneron who obtain reimbursement for their drugs through any Medicare Part C plan must comply with the Anti-Kickback Statute.

66. The federal Anti-Kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal healthcare program.

67. A pharmaceutical manufacturer's waiver of or payment of the cost-sharing obligations of members—including through inappropriate charitable arrangements—constitutes a violation of the federal Anti-Kickback statute whether the patient at issue is enrolled in a Medicare Part A, Part B, Part C or Part D plan.

68. The federal government has issued numerous guidance documents (Bulletins) that explain what sorts of arrangements between pharmaceutical companies and charities violate the Anti-Kickback statute.

69. In 2005, the Office of Inspector General (OIG) issued a Bulletin[7] directed specifically to patient access programs (PAPs) that provide charitable cost-sharing assistance. Issued just before the Medicare Part D program went into effect, OIG noted that patient access programs (PAP) that were funded by pharmaceutical manufacturers and used to subsidize Part D cost-sharing amounts present heightened risks under the Anti-Kickback statute. That bulletin noted that in certain circumstances, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers could be appropriate, even if the charities received manufacturer contributions but only so long as certain safeguards were met.

[7] 70 Fed. Reg. 70623 (November 22, 2005).

70. Specifically, OIG noted that "[f]or purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded, or controlled by a manufacturer or any of its affiliates, to be a *bona fide*, independent charity, because interposition of the entity would not sever the nexus between patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer . . . and would provide subsidies only for the manufacturer's products."

71. OIG went on to explain, "where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs."

72. OIG also expressed concerns that the use of cost-sharing subsidies to shield beneficiaries from economic effects of drug pricing would eliminate a market safeguard against inflated prices.

73. OIG provided a blueprint for a patient-assistance program that would comply with federal law. According to OIG, all of the following should be true for such a program to be compliant:

a. The third-party administering the program is an independent, *bona fide*, charity;

b. Neither the manufacturer or any affiliate exerts any direct or indirect influence or control over the charity or program;

c. Assistance is awarded in a truly independent manner that severs any link between the manufacturer's funding and the beneficiary;

d. The charity awards assistance without regard to the beneficiary's choice of product, provider, practitioner or supplier;

e. Assistance is based on a reasonable, verifiable, and uniform measure of financial need applied in a consistent manner;

f. The manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products; and

g. The manufacturer does not earmark its donations for narrow disease categories (or for use of a specific drug) which, for example, are defined by reference to specific symptoms, severity of symptoms, or method of administration of drugs. Manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.

74. In 2014, OIG issued a Supplemental Bulletin on pharmaceutical companies' "indirect remuneration to patients" through "contributions to PAP[s]" operated by independent charities.[8] In that Supplemental Bulletin, OIG reiterated that "[i]f a donation is made to a PAP to induce the PAP to . . . arrange for the purchase of the donor's federally reimbursable items, the [federal Anti-Kickback] statute could be violated."

75. In the Supplemental Bulletin, OIG also emphasized that independent charities cannot "give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP."

[8] 79 Fed. Reg. 31120-31123 (May 30, 2014).

76. The federal Anti-Kickback statute is supplemented by a number of state laws that prohibit the same type of conduct. States with similar prohibitions include Texas, Florida, Illinois, California, Minnesota and others. Many of these state statutes prohibit causing the submission of claims tainted by kickbacks to insurers even outside of the context of a governmental health insurance program.

77. In addition to the Anti-Kickback statute, the False Claims Act (31 U.S.C. § 3729) prohibits knowingly causing the submission of fraudulent claims for payment to a federal health program like Medicare.

78. Pursuant to 31 U.S.C. § 3729(a), claims for reimbursement to the Medicare program that result in violation of the federal Anti-Kickback statute constitute *per se* violations of the False Claims Act.

REGENERON'S FRAUDULENT SCHEME

79. Beginning in 2013, Regeneron embarked on a fraudulent scheme designed to subvert the cost-sharing obligations set out in the contracts discussed above.

80. Regeneron covertly funneled illegal kickbacks to patients through a purportedly independent charity, the CDF, to ensure that these contractual obligations would not restrain Eylea's price. This interfered with the contracts United maintains with its Medicare insureds.

81. The coordination of conduct and sharing of information between the CDF and Regeneron also violated the legal prohibitions discussed above.

82. Regeneron was thus able to charge significantly higher prices for Eylea and bilk United out of tens, if not, hundreds of millions of dollars through its unlawful conduct.

83. Documents unearthed by the Department of Justice, discussed below, provide a detailed look into the inception and execution of Regeneron's scheme.

Regeneron's Consultants Advise Regeneron that it can Raise Eylea's Price if a Patient Charity Pays Patient Cost-Sharing Obligations

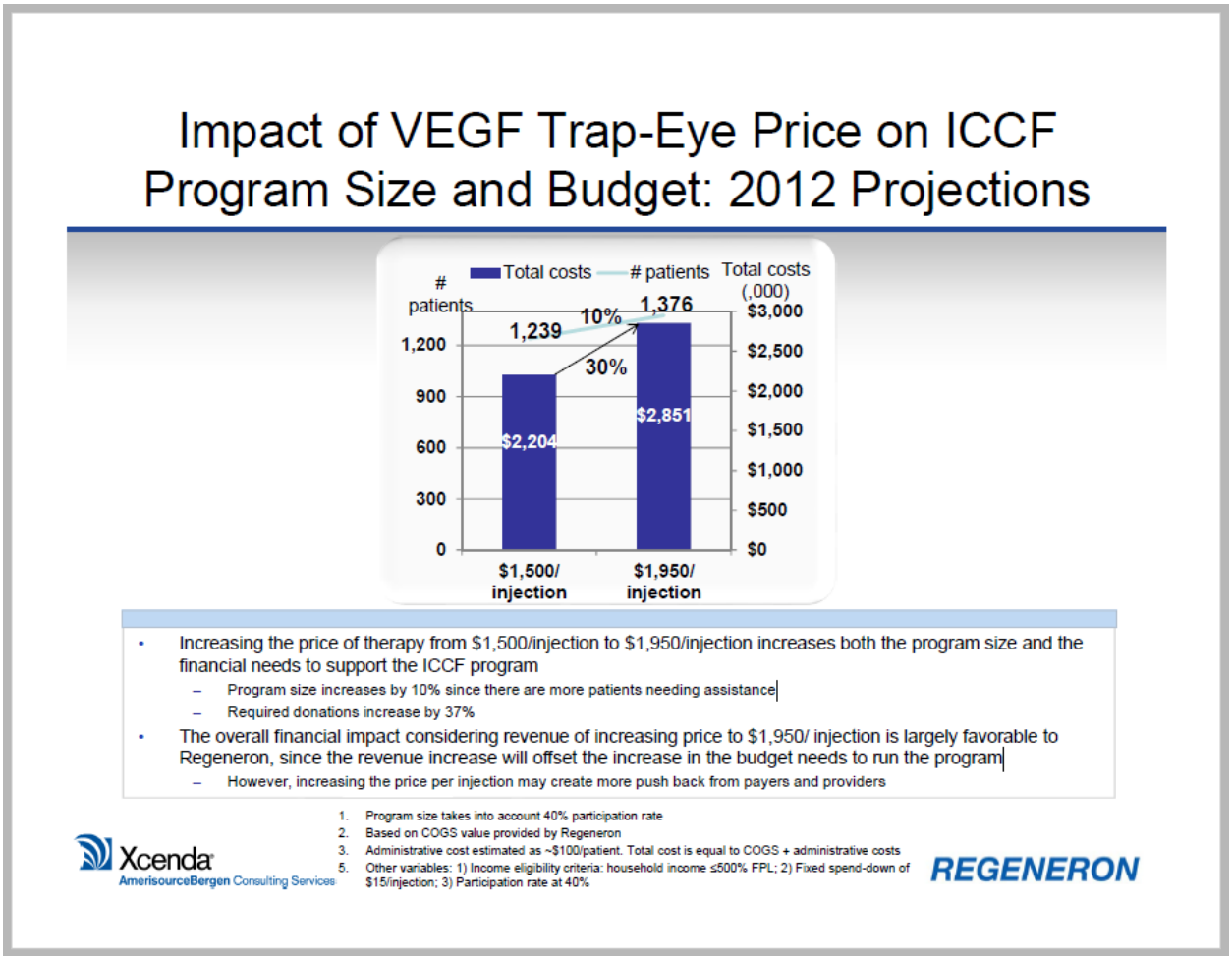
84. In the months leading up to the FDA's approval of Eylea, Regeneron retained a division of the AmerisourceBergin Corporation, Xcenda, to assist it in bringing Eylea to market. Among other things, Xcenda performed analyses and advised Regeneron on the pricing of Eylea and the impact of patient charities on the same. This work culminated in a presentation dated May 12, 2011. *See* Ex. B.

85. When Xcenda provided Regeneron with its analysis, Regeneron was considering setting the price of Eylea at $1,500 a dose.

86. Xcenda advised Regeneron that, with the help of a patient charity, Regeneron could potentially increase that price by as much as 30%, to $1,950 a dose.

87. Xcenda noted that most (77%) of those suffering from wet AMD are Medicare beneficiaries. Xcenda estimated that Regeneron would have to pay $3 million in 2012 to cover the cost sharing obligations of this patient population.

88. Xcenda's analysis showed that, if Regeneron could pay this sum through a patient charity, the "financial impact" of "increasing [the] price" of Eylea from $1,500 "to $1,950/ injection [would be] largely favorable to Regeneron." Although Regeneron would have to dedicate more resources "since there [would be] more patients needing assistance" at the higher price, and as a result the "[r]equired donations increase[d] by 37%," the "revenue increase will offset the increase in the budget needs to run the [patient charity] program." Ex. B at 41. The following is an image of this slide:



Ex. B at 41

89. Despite the foregoing, Xcenda recognized that there were impediments to increased profits—assuming Regeneron conducted itself lawfully. In particular, as Xcenda observed, there are strict "federal restrictions" on paying the cost-sharing obligations of Medicare patients, which prohibit coordinating with patient charities. Accordingly, Xcenda advised Regeneron that the "Cons" of using a patient charity included "[u]nknown allocation of funds among products in the same therapeutic space." Ex. B at 30. In other words, a truly independent charity would use Regeneron's donations to help AMD patients whether or not they purchased Eylea. Xcenda similarly cautioned Regeneron that "[d]onations to copay charities have several limitations, such

as . . . limited data provided by the foundation, and no control over operations of the fund (e.g., income eligibility criteria or spend-down).” Ex. B at 57.

90. Despite that risk, Xcenda concluded that patient charities presented “the most financially viable” option. Ex. B at 57. In particular, this would permit Regeneron to increase profits, whereas other means of supporting patients with financial needs—such as providing free Eylea to patients who could not afford it—would hurt Regeneron’s bottom line.

91. Based on Xcenda’s advice, Regeneron ultimately priced Eylea at $1,850, nearly 25% higher than it would have otherwise and 33 times higher than an equally effective competitor drug.

Regeneron’s Enters into a Conspiracy with the Chronic Disease Foundation to Pay Patient Cost-Sharing Obligations

92. Regeneron understood that its drug would compete with Avastin, a much cheaper alternative of comparable effectiveness. For that reason, Eylea’s success depended on removing the barrier posed by patients’ cost sensitivity. Cynthia Sherman, who served as a Senior Director for Reimbursement at Regeneron at the time of Eylea’s launch, affirmed in testimony given to the Department of Justice that “people understood that if co-pay assistance was not available for Eylea or Lucentis patients, that patients with wet AMD would end up on Avastin.” Sherman continued, “that’s why they wanted to have a managed care co-pay program.” Accordingly, Regeneron adopted Xcenda’s proposal that it establish a relationship with a patient charity.

93. Out of the list of potential patient charities recommended by Xcenda, Regeneron ultimately settled on the CDF (now operating as “Good Days”).

94. The CDF was founded in 2004 and began providing patient cost-sharing assistance using donations from pharmaceutical companies beginning in 2006.

95. The CDF provides grants to cover patient cost-sharing obligations for specific drugs when used to treat certain chronic health conditions. Physicians administering such drugs submit claims to the CDF to cover the portion of the drug's cost usually borne by the patient. The CDF then pays the physician directly.

96. Grants are drawn from discrete funds dedicated to treating specific health conditions. Thus if the fund that covers a certain condition is depleted, cost-sharing assistance from the CDF is no longer available for that condition.

97. As of 2011, the CDF approved a fund to cover the cost of treating AMD using Eylea and Lucentis, but not Avastin. As a result, the availability of CDF funding made Eylea *cheaper* than Avastin from the perspective of patients, despite the fact that Eylea is in reality more than 33 times as expensive. But CDF funding also provided the same potential benefit with respect to Lucentis, Eylea's competitor.

98. As a result, Regeneron was initially conservative in its donations to the CDF. Despite Xcenda's recommendation that Regeneron donate $3 million in 2012, Regeneron donated only $600,000. In testimony to the Department of Justice, Sherman explained that "Regeneron did not want to pay for Lucentis's co-pay."

99. The success of Eylea, however, created significant demand for charitable assistance.

100. Accordingly, in 2012, Regeneron hatched a scheme to coordinate with the CDF so that its donations would benefit only Eylea users.

101. On July 9, 2012, Robert Krukowski—Regeneron's Senior Manager for Reimbursement & Managed Markets Marketing—sent an email on that topic to William Daniels, a member of his staff. Krukowski asked Daniels if, in his recent communications with Clorinda Walley, CDF's Executive Director, Walley had "mentioned anything along the lines [of]

[Regeneron] upping [its] contribution in 2013." Krukowski noted that Regeneron "probably should up [its] overall contribution to CDF given [Eylea's] performance," but that it would be "hard to just pick a number." Ex. C.

102. Two weeks later, on July 23, 2012, Daniels emailed Walley asking if she could speak with him to "review the numbers" in advance of a meeting at which he would have to "justify [his] request for [Regeneron's] 2013 donation" to CDF. Ex. D. Walley agreed to meet for that purpose. *Id.*

103. The following day, Walley sent Daniels an email with the subject line "Regeneron Projections 2013," which attached a spreadsheet with the same title. This spreadsheet detailed the CDF's spending on Eylea patients, and included projections concerning the amount the CDF would need to cover the cost-sharing obligations of Eylea patients, and *only* Eylea patients, in 2013. *See* Ex. E.

104. Daniels forwarded this email and spreadsheet to Krukowski, stating that the CDF's "2013 projection is pretty much our 2012 actuals." *Id.*

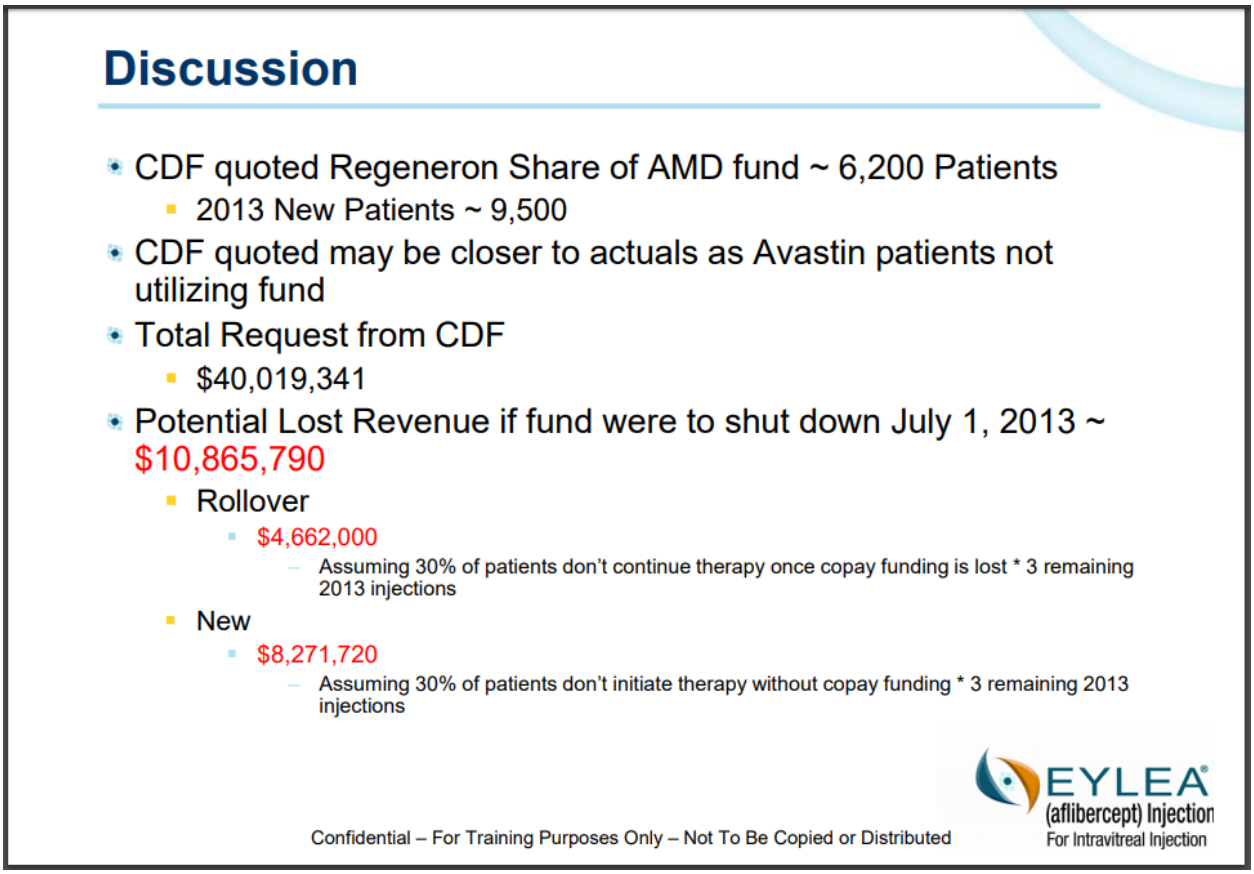
105. Daniels felt that Regeneron was unlikely to approve a donation in the amount CDF outlined ($40 million). Accordingly, he combined the information he received from CDF with internal business information to revise the estimates downward. He determined that Regeneron could likely fund the cost-sharing obligations of the existing patient base with a donation of roughly $5.6 million, and new patients with a donation of between $11.5 and $19.2 million. *See* Ex. F. Daniels estimated that the return on investment with respect to existing patients alone would be roughly $24.8 million, more than quadrupling Regeneron's money.

106. Daniels forwarded his estimates to Krukowski in mid-August, stating that he believed Regeneron needed "to try and budget as much as possible" for CDF donations to avoid

the total depletion of the CDF fund. *Id*. Krukowski replied that Daniels had "some good points," requesting that Daniels put together a slide deck illustrating the consequences "if CDF isn't funded for a portion of the year," to be shared with Regeneron's top executives. *Id.* Krukowski then scheduled a meeting regarding the "ROI" and "risks" of CDF donations with Daniels and Robert Terifay, Regeneron's Vice President, Commercial. Ex. G.

107. On August 16, 2012, Daniels sent Krukowski and Robert Davis—Regeneron's Executive Director and Head of Trade—a summary of Regeneron's situation vis-à-vis its 2013 donation to the CDF. Daniels included a chart labeled "Chronic Disease Fund Request & Rationale," with a comparison of the CDF's numbers to his "Regeneron Modified Estimate of CDF Need." Ex. H. The chart noted that failure to adequately fund the CDF could mean millions of dollars in "potential lost sales." *Id.*

108. On August 27, 2012, Daniels circulated a slide deck to Krukowski that streamlined his summary and chart. Among other things, the chart noted that "CDF management has communicated that for 2013, if every donor doesn't cover their market share the fund will be closed." Ex. I. The slide deck reiterated that Regeneron faced millions of dollars in potential lost profits if it did not adequately fund the CDF. That slide is reproduced below:



Ex. I at 9

109. Shortly before the meeting scheduled to discuss Regeneron's 2013 donation to the CDF, Daniels circulated a revised slide deck, which adjusted upward the "[p]otential lost revenue" if the CDF were not adequately funded. Ex. J.

110. On October 8, 2012, Daniels and Krukowski had the planned meeting with Terifay. Terifay rejected Daniels' assessment and took the position that Regeneron would donate only $2.5 million to the CDF in 2013. Daniels subsequently conveyed that to Walley.

111. Walley responded with an email dated December 19, 2012. Ex. K. In that email, Walley explained that the $2.5 million donation would be insufficient, and that the fund would likely run out by the end of January 2013. *Id.* Walley attached a spreadsheet titled "Regeneron

Projections 2013_1219212" which set out a revised estimate of the amount required to cover the cost-sharing obligations of Eylea users. *Id.* The revised estimate was very similar to Daniels' projections, stating that Regeneron would have to donate $24,843,956 to cover the cost-sharing obligations of Eylea users. *Id.*

112. Later that day, Krukowski emailed Cathy Casey—Regeneron's Senior Director for Reimbursement Strategy—voicing his concern about the level of Regeneron's CDF donation. Ex. L. Krukowski stated that the CDF had "provided [Regeneron] more information on Gene[ntech] funding and we really need to make everyone aware of the risks and what is our true commitment." Although Terifay had since agreed to increase the donation to $10 million, Krukowski still felt "confident that we still have an issue at $10 mil based up[on] what CDF is stating and has shared with us." *Id.*

113. On January 3, 2013, Krukowski, Daniels, and Casey met with Terifay to discuss "new information" from the CDF. *See* Ex. M. Following that meeting, Krukowski sent an email to Walley stating that Daniels had used the information supplied by CDF to explain to Regeneron executives (including Terifay) that Regeneron "potentially need[ed] ~25Mil to adequately fund our patient responsibility for 2013," and that Terifay "finally underst[ood] what [Regeneron's] total funding commitment w[ould] be for this year." Ex. N. Krukowski stated that Terifay planned to present the information from the CDF to "the boys," referring to other top Regeneron executives.

114. The following day, Christopher Fenimore, Regeneron's Vice President of Financial Planning, stated in an email to Terifay and others that Terifay had "walked [him] through the logic" and that Regeneron's executives "agreed to put $25MM" into Regeneron's 2013 donation

to CDF. Ex. O. In short, Regeneron agreed to pay almost exactly the amount the CDF requested to cover the cost-sharing obligations of Eylea users.

115. As detailed above, Regeneron agreed to pay these amounts only because the CDF indicated that it would use these amounts to pay the cost-sharing obligations of Eylea users, as opposed to the cost-sharing obligations of patients using other drugs.

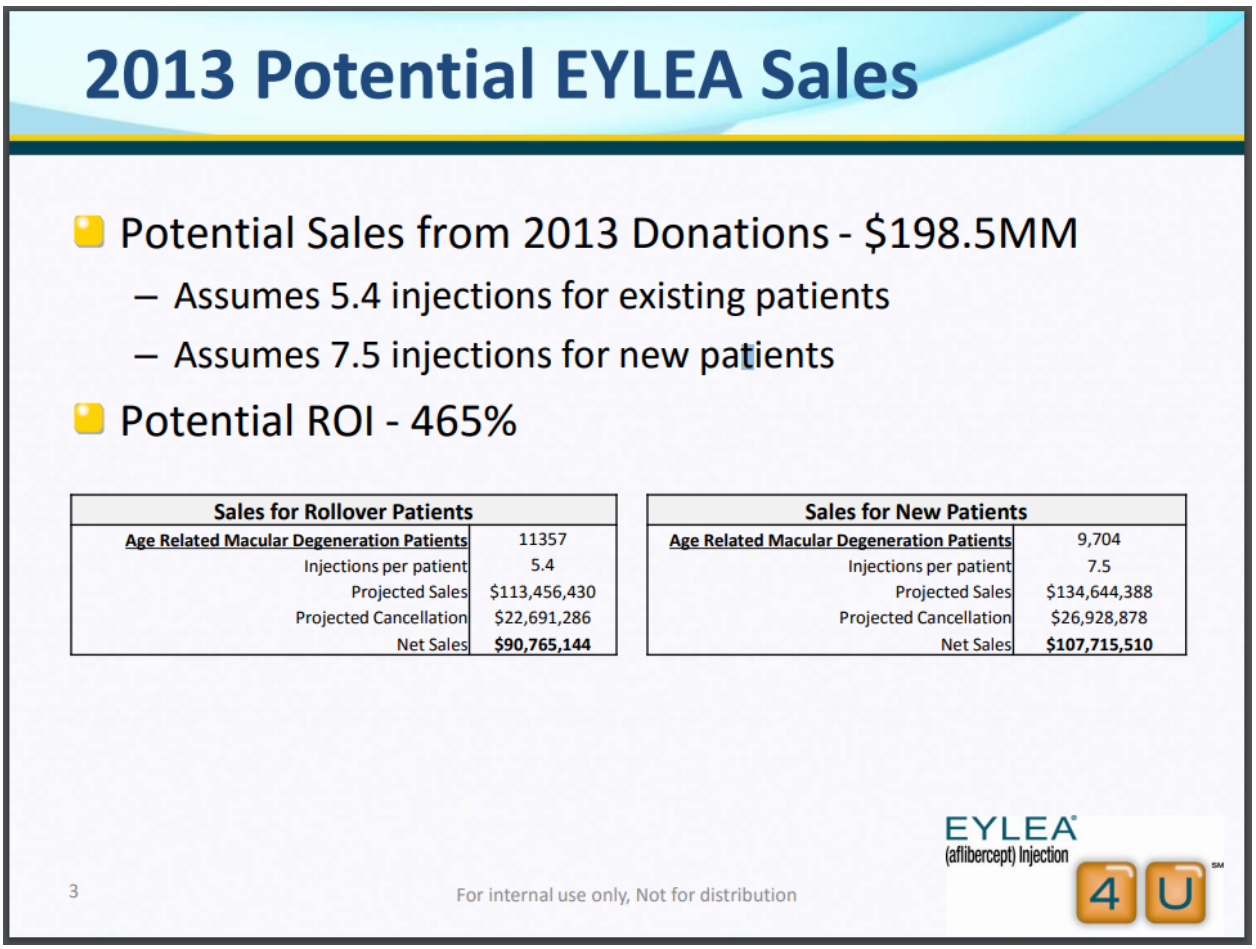
116. Regeneron would not have donated these amounts, or future amounts, had it not reached an understanding with the CDF that the CDF would use Regeneron's donations to cover the cost-sharing obligations of patients using Eylea, as opposed to other drugs.

117. Although the CDF commingled Regeneron's donations with other funds, Regeneron understood from its communications with the CDF that ultimately, on at least an annual basis, there would be a one-to-one correlation between the amounts Regeneron put into the fund and the amounts the CDF paid out to cover the cost-sharing obligations of Eylea patients.

118. In the first half of 2013, Regeneron donated $5 million on February 13 and $7.5 million on May 1, totaling $12.5 million—the first half of the promised donation.

119. But as it turned out, this increased donation still was not enough. On June 18, 2013, Walley sent Daniels a spreadsheet with "updated projections," showing that CDF would need $34,540,204 to fund the cost-sharing obligations of Eylea users in 2013. Ex. P.

120. Daniels then sent a slide deck to Krukowski on June 24, 2013, which used the information conveyed to him by the CDF to explain why Regeneron should adjust its donation for 2013 upward to $35 million. The slide deck noted that the CDF had "paid out $32.6MM through 6/3/13," out of which 41% was attributable to Eylea. Ex. Q. Daniels extrapolated that "Potential Sales from 2013 Donations" totaled "$198.5MM," and that Regeneron enjoyed a "Potential ROI" of "465%" on these donations. *Id.* This slide is reproduced below.



2013 Potential EYLEA Sales

- Potential Sales from 2013 Donations - $198.5MM
  - Assumes 5.4 injections for existing patients
  - Assumes 7.5 injections for new patients
- Potential ROI - 465%

Sales for Rollover Patients	
Age Related Macular Degeneration Patients	11357
Injections per patient	5.4
Projected Sales	$113,456,430
Projected Cancellation	$22,691,286
Net Sales	**$90,765,144**

Sales for New Patients	
Age Related Macular Degeneration Patients	9,704
Injections per patient	7.5
Projected Sales	$134,644,388
Projected Cancellation	$26,928,878
Net Sales	**$107,715,510**

3

For internal use only, Not for distribution

EYLEA® (aflibercept) Injection 4 U℠

Ex. Q at 4

121. Daniels presented this slide deck to Fenimore on June 26, 2013, after which Fenimore forwarded the slides to Regeneron's CFO with the note "this makes sense to me." Ex. R. Later that day, Stephen Dressel, Regeneron's Director of Commercial Finance, notified Daniels in an email that Regeneron would increase its donation to $35 million in 2013. Ex. S. Fenimore confirmed this plan on July 9, 2013 in emails to Regeneron's CFO. Ex. T. Again, Regeneron agreed to pay almost exactly what the CDF requested.

122. Regeneron followed through, paying $7.5 million on August 21, $10 million on September 25, and $5 million on October 1, bringing its total donations for 2013 up to the $35 million requested by the CDF.

123. The coordination between Regeneron and the CDF did not end there.

124. On January 3, 2014, Krukowski sent Daniels an email regarding further coordination with the CDF in 2014. Daniels responded that he had spoken with Walley and "should have her Q1 request" later that day. Ex. U. Shortly thereafter, Daniels forwarded Krukoski and others an email from Walley, which attached a spreadsheet estimating the amount the CDF would require to fund Eylea patients, and only Eylea patients, in 2014. Ex. V. Walley's email included the following summary of the CDF's estimated need:

Please find attached an updated AMD projection need for 2014 which includes CDF's need to facilitate assistance for renewal and new patients in the 1st quarter. I have summarized below.

2014 Renewals	$ 29,434,885
2013 Roll-Over	$ 9,500,000
Total 2014 ReEnrollment Need	$ 19,934,885
Total 2014 1st Qtr Need	$ 5,495,226
Sum of Need Existing/New 1st Qtr 2014	$ 25,430,111

Ex. V at 1

125. Daniels' email summarized the CDF's rationale for its request, noting that funds leftover from Regeneron's "donations" in the prior year would "roll over" into 2014, bringing the total funding request for the first quarter of 2014 to $25,430,111. Daniels further explained that the CDF asked Regeneron to donate a total of approximately $39 million in 2014. Ex. V. Daniels ultimately offered sworn testimony to the Department of Justice that he understood the CDF would use these amounts solely to cover the cost-sharing obligations of Eylea patients.

126. Three days later, Daniels formally recommended to Terifay and others via email that Regeneron pay $25.5 million—almost exactly what the CDF requested—in two installments of $12.75 million during the first quarter of 2014. Ex. W. Regeneron's executives approved the first installment in an email dated January 10, 2014, Ex. X, and Regeneron donated $12.5 million to the CDF on January 15, 2014.

127. During this time, Regeneron's "donations" to the CDF correlated almost exactly with the CDF's outlay on Eylea, confirming that the CDF served as a conduit between Regeneron and Eylea users.

128. On information and belief, the scheme described above continued in much the same manner thereafter through to the present day. But due to increased scrutiny of kickback schemes like that described above by federal authorities, Regeneron became more careful about creating a written record of its illegal dealings with the CDF.

129. The need for this illegal relationship to maintain Eylea's inflated price, however, was clear to Regeneron. Indeed, just one day before Regeneron's executives approved the January 2014 donation of $12.5 million, Daniels and Krukowski received an email from a Regeneron sales associate who stated that a large provider had heard that the CDF had run out of funding for Eylea. As a result, that provider had begun "putting patients only on Avastin," meaning lost sales for Regeneron. Ex. Y. It was thus clear that if Regeneron did not cover patients' cost-sharing obligations, its $1,850-per-dose anti-VEGF drug could not compete with an equally effective drug costing only $55 per dose.

130. On information and belief, the specific overt acts Regeneron undertook to perpetuate this unlawful scheme during this period and thereafter included: (a) routinely obtaining information from the CDF regarding patients receiving Eylea, including United members, along with the amounts necessary to eliminate their relevant cost-sharing obligations; (b) calculating payments to the CDF to specifically cover, and which correspond to, the financial needs of patients taking Eylea, including United members; (c) confirming that the revenue generated by Regeneron's funneling of funds through the CDF would far exceed the amount of payments Regeneron made to the CDF; (d) making massive payments to the CDF to advance its unlawful

scheme; and (e) ensuring that those payments were directed to satisfy the cost-sharing obligations of patients receiving Eylea, including United members.

131. On information and belief, the overt acts the CDF undertook to perpetuate this unlawful scheme during the period described above and thereafter include: (a) routinely providing Regeneron with information describing the patients prescribed Eylea who were receiving assistance from the CDF, including United members, and how much money was necessary to eliminate their relevant cost-sharing obligations (so that Regeneron could calculate and send massive, corresponding payments to the CDF); and (b) routing the payments the CDF received from Regeneron directly to patients receiving Eylea, including United members, in order to eliminate their relevant cost-sharing obligations.

132. The concerted actions of Regeneron and the CDF, and the unlawful acts they perpetrated, directly and proximately caused significant damages to United in the form of payments United made for Eylea that United would not otherwise have paid.

Regeneron Actively Conceals the Conspiracy

133. Regeneron's leadership knew that the company's payments to the CDF violated the law in light of the parties' information sharing and mutual understanding of how the CDF would use funds it received from Regeneron. Indeed, the executives who approved this relationship received specific, repeated warnings from their subordinates.

134. Sherman testified to the Department of Justice that, early on, she warned Regeneron executives, including Terifay and Dressel, that Regeneron could not legally "get a breakdown of [its] spend by EYLEA users" from CDF, "designate [Regeneron's] donations specifically for [Eylea]," or "get actual utilization data from the foundation." Sherman further testified that these executives rejected her warnings and insisted on an "overview of who [Regeneron] [was]

providing [its] financial assistance to." Davis offered a similar warning to Daniels and Krukowski in October of 2012. And Daniels himself circulated a copy of an OIG opinion specifically forbidding the behaviors discussed above[9] to Krukowski in December of 2012.

135. Were there any doubt that Regeneron's leadership understood the company's conduct to be illegal, top Regeneron executives deliberately deceived internal auditors as to Regeneron's relationship with the CDF.

136. For example, in response to a February 2013 email from company auditors regarding what information Regeneron received from the CDF, Terifay responded that Regeneron "ha[d] no rights to information of any sort on disposition of funds" from the CDF. He asserted that Regeneron "[could not] ask for any information from the CDF," and thus merely "gave a charitable donation." Before sending this email, Terifay misleadingly edited an earlier email in the chain from Daniels to elide the fact that Regeneron was in fact receiving the very information at issue. Ex. Z.

137. In November 2013, Krukowski and Daniels similarly misled company auditors at a meeting to believe Daniels had not been having "conversations with CDF concerning product level data." Ex. AA. They further misrepresented that Regeneron had received only aggregate reports from the CDF *without* Eylea-specific data. Daniels furthered this deception by requesting such a report from Walley, Ex. AB, which he then forwarded to an auditor to create the false impression that Regeneron received reports from the CDF only in this format. Ex. AC.

138. Shortly thereafter, Daniels sent the company auditor an email falsely asserting that Regeneron did not "receive any other reports or data" besides the aggregate report Daniels

[9] 70 Fed. Reg. 70623 (Nov. 22, 2005)

provided. Ex. AD. He later admitted in sworn testimony to the Department of Justice that this was a lie, which he sent to company auditors because he "was told to" by Terifay.

139. On information and belief, Regeneron's executives lied to company auditors because those auditors might have blown the whistle on the company's illegal activities. In doing so, Regeneron's executives took active steps to conceal the nature of their relationship with the CDF from United and other Medicare payors.

140. On information and belief, the foregoing are just some examples of a larger pattern of behavior whereby Regeneron actively concealed its illegal scheme.

141. Regeneron attempted to conceal its scheme because it knew that its relationship with the CDF tainted any related claims for Eylea submitted to United and other payors with illegal kickbacks. As such, those claims would not be payable under federal law and United's contracts with its insureds. Regeneron knew that United and other payors would not pay claims for Eylea if they understood those claims to be tainted by an illegal kickback scheme.

142. Regeneron also knew that the providers who administered Eylea would submit claims to United, and in doing so would certify that the claims were not tainted by illegal kickbacks. Regeneron understood that, where the CDF used Regeneron's "donations" to pay patients' cost-sharing obligations, these certifications were rendered false, and that United and other payors would be unaware of that fact.

143. Regeneron knew and intended that these certifications, which Regeneron knew to be false, would mislead United and other Medicare payors to pay tainted claims for Eylea treatment.

144. Regeneron understood that, by concealing its scheme, it could deceive United into paying for Eylea treatment contrary to federal law and the cost-sharing provisions of United's contracts with its members, which would ultimately generate massive revenue for Regeneron.

Regeneron Uses its Kickback Scheme to Induce Eylea Prescriptions

145. As discussed above, when physicians understand their patients will bear the cost of Eylea, those physicians instead prescribed the much-cheaper Avastin. Regeneron had in fact observed that providers would begin "putting patients only on Avastin" if they believed their patients would bear Eylea's cost. *See* Ex. Y.

146. For that reason, Regeneron disseminated information about the availability of "charitable" funding from the CDF, even as it concealed the true nature of that funding.

147. In or around 2012, just as it began coordinating with the CDF, Regeneron launched a program dubbed EYLEA4U, the purpose of which was (and is) to maximize sales of Eylea, including by ensuring that patients do not bear the cost of the drug.

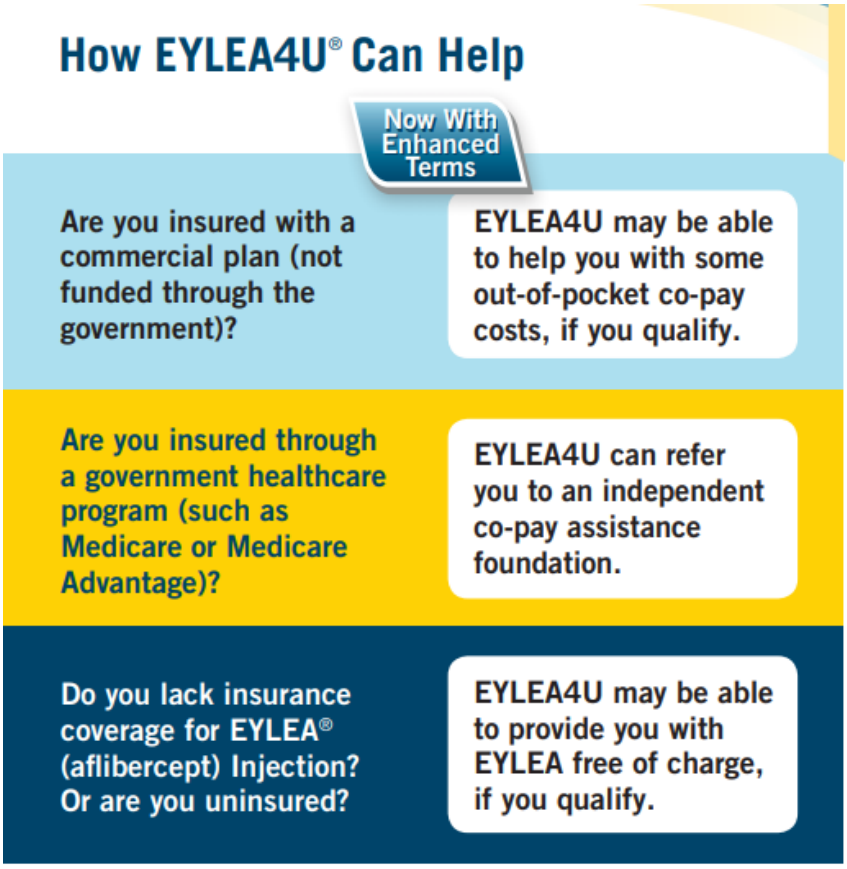
148. Regeneron selected contractors from the Lash Group—a pharmaceutical market access and patient support consultancy—to run the EYLEA4U program. Notably, the Lash Group is also part of the AmerisourceBergin Corporation, and is a sister company to Xcenda, which helped Regeneron hatch its scheme.

149. Regeneron marketed EYLEA4U to physicians with promises to "[h]elp[ ] to meet the reimbursement and copay assistance needs of you and your patients." Ex. AE at 2.

150. Physicians submitted insurance information for their patients to EYLEA4U before their patients began Eylea treatment, which Regeneron used to "determine if [the patient] [was] eligible to participate in Regeneron's reimbursement assistance program, patient assistance program and other support programs (together, 'EYLEA4U® Programs')." Ex. AF at 2.

151. On information and belief, EYLEA4U referred most or all Medicare patients, who comprised the large majority of Eylea users, to the CDF for "charitable" cost-sharing assistance.

152. In referring patients to the CDF, Regeneron falsely represented the CDF to be "an independent co-pay assistance foundation," as in the below brochure:



Ex. AG at 3

153. Regeneron further falsely claimed on various websites and in its promotional materials that "Regeneron does not influence or control the operations of patient assistance programs through independent charitable foundations." Ex. AH at 2.

154. Regeneron publicized these and similar falsehoods to patients, physicians, and the public at large to elide its illegal kickback scheme with the CDF.

155. For Medicare patients referred to the CDF through EYLEA4U, Regeneron would "[f]ollow up with . . . the foundation until a decision [was] made on [the patient's]"application, and would "[l]et [the patient's] doctor's office know that [the patient] ha[d] applied and provide an update with the final decision." Ex. AG at 6. Regeneron thus created a pipeline to connect

Eylea patients with the CDF, and worked directly with the CDF to ensure that Eylea patients would receive the funds Regeneron "donated."

156. The EYLEA4U program served not only to connect Eylea patients with the CDF, but to assure their physicians of the availability of funding to cover cost-sharing obligations for Eylea. Physicians understood that if they prescribed Eylea, Regeneron would ensure that their patients qualified for CDF funding through the EYLEA4U program. Doctors relied on this knowledge in deciding whether to prescribe Eylea over the much-cheaper Avastin.

157. Prescribing physicians further obtained information regarding the availability of "charitable" funding directly from the CDF when deciding whether to prescribe Eylea or Avastin. Indeed, Regeneron knew that physicians obtained information from "CDF rep[s]" about the availability of funding for Eylea and used this information to determine whether to prescribe Eylea or the much-cheaper Avastin. Ex. Y. Regeneron encouraged this by disseminating contact information for the CDF through the EYLEA4U program.

158. On information and belief, as a result of Regeneron's efforts, the availability of "charitable" funding for Eylea became well-known among prescribing physicians. Thus, even physicians who did not have direct contact with the EYLEA4U program learned of this funding from other sources and accounted for it in deciding whether to prescribe Eylea over Avastin.

159. The availability of this "charitable" funding was material to physicians' decisions in prescribing Eylea over Avastin, and patients' decisions in undertaking treatment using Eylea over Avastin. Indeed, most physicians and patients chose Avastin over Eylea in the absence of this funding. Regeneron's illegal payments, and its dissemination of misleading information concerning the resulting funds, improperly induced Eylea prescriptions in at least three ways.

160. First, as a matter of practical necessity, doctors will prescribe treatments their patients can afford over those their patients cannot afford. This is the intended result of cost-sharing obligations imposed by United and other insurers, meant to restrain drug prices and encourage economical choices. Physicians prescribe Avastin over Eylea in the absence of patient cost-sharing assistance because most patients can far more easily afford Avastin than Eylea, and the drugs are equally effective. By making illegal payments to the CDF, and by advising physicians of the availability of the resulting funds, Regeneron and its confederates induced prescriptions of Eylea by effectively rendering it "cheaper" to patients than Avastin.

161. Second, patients will not agree to treatment they cannot afford when there are other, affordable treatments available. On information and belief, both EYLEA4U representatives and physicians would regularly share information regarding the availability of cost-sharing assistance through the CDF with patients when patients were deciding whether to undergo Eylea or Avastin treatment. The availability of this funding was material to patients' decisions to undertake Eylea treatment, rather than its much-cheaper alternative. Regeneron's illegal payments to the CDF, and its dissemination of misleading information about the resulting funds, induced patients to undergo Eylea treatment by effectively rendering it "cheaper" to patients than Avastin.

162. Third, physicians have economic incentives to prescribe Eylea over Avastin when their patients are able to pay for Eylea, and vice versa. Physicians typically enjoy higher reimbursement from insurers like United for prescribing and administering Eylea relative to Avastin. But physicians cannot realize those profits if their patients are unable to pay for Eylea treatment. Regeneron's illegal payments to eliminate patient cost-sharing obligations, and its dissemination of misleading information about the resulting funds, induced Eylea prescriptions by allowing doctors to realize these higher reimbursements despite Eylea's greater cost.

163. Regeneron undertook its scheme intending to induce Eylea prescriptions in at least the foregoing ways. Indeed, Regeneron embarked on its scheme based on data from Xcenda indicating that, by using a charity to eliminate patient cost-sharing obligations, Regeneron could induce Eylea prescriptions even if it charged an artificially high price for the drug. Regeneron's "ROI" analyses further confirm that Regeneron understood its scheme would induce doctors to prescribe Eylea, and patients to undergo Eylea treatment.

Regeneron Facilitates Insurance Claims for Eylea

164. While Regeneron sells Eylea to wholesalers in the first instance, Regeneron knew "[s]ales in the United States of [Regeneron's] marketed products are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid."[10]

165. Another function of EYLEA4U was to ensure that insurers, including United, paid claims that physicians submitted for Eylea.

166. Regeneron monitored and facilitated payments by insurers, including United, for Eylea claims that Regeneron knew to be tainted by its illegal kickback scheme.

167. In particular, Regeneron offered "reimbursement support" for physicians who prescribed Eylea through the EYLEA4U program.

168. The suite of services Regeneron offered physicians included, among other things, a "thorough [benefits investigation] that—within 2 business days—summarizes [the] patient's coverage, [prior authorization] requirements, cost responsibility, and any additional coverage

[10] Regeneron, 2019 Form 10-K Annual Report, at 24 (Feb. 7, 2020), https://tinyurl.com/y3zxyfkv.

information" related to Eylea. Ex. AI at 2. As part of this process, Regeneron representatives contacted insurers, including United, to verify patients' benefits related to Eylea.

169. Regeneron "recommended" to physicians that, "[b]efore a patient starts EYLEA treatment," the physician "conduct a [benefits investigation] by completing and submitting an EYLEA4U® Enrollment Form," which would further permit Regeneron to direct that patient to cost-sharing assistance through the CDF or its copay card program. Ex. AI at 1.

170. Another service Regeneron provided through the EYLEA4U program was that it would "[r]eview the status of an EYLEA claim with the patient's insurer." Ex. AI at 3. As part of this process, Regeneron representatives contacted insurers, including United, to facilitate the payment of claims for Eylea.

171. Regeneron further offered "reimbursement support" to prescribing physicians by supplying information to help "prepare" claims and, when insurers like United denied Eylea claims, by "provid[ing] . . . information on how to resolve the issue." Ex. AI at 2.

172. On information and belief, Regeneron representatives regularly contacted United to facilitate the payment of claims for Eylea in the manner set forth above, beginning in or around 2012 and continuing to the present day.

173. None of these Regeneron representatives ever informed United of Regeneron's fraudulent scheme.

Regeneron Reaps Windfall Profits from Sales of Eylea

174. Regeneron's scheme worked precisely as planned. Regeneron maintained an artificially high price for Eylea and reaped windfall profits for years.

175. Since 2011, sales of Eylea have generated *$22.4 billion* in revenue, representing at least 60% of Regeneron's annual revenue. Regeneron has thus enjoyed massive profits stemming from the illegal scheme discussed above.

176. In 2013, Regeneron warned investors that its revenues were concentrated in Eylea and that a drop in sales would lead to material harm.[11] Regeneron further noted that Eylea faced "strong competition" from Lucentis and Avastin. In particular, it noted that ophthalmologists were successfully using Avastin off-label to treat wet AMD, and that Avastin's relatively low cost presented a significant challenge to Eylea.

177. Regeneron's revenue concentration from Eylea only increased over time, even as Eylea's market positon grew more tenuous. In 2015, Regeneron again warned investors that it depended on Eylea for a large portion of annual revenues, and that Eylea faced even greater competition from recently approved drugs.[12] Regeneron similarly noted that the commercial success of Eylea was heavily dependent on Regeneron's ability to persuade prescribers to choose Eylea over the competition.

178. The foregoing gave Regeneron a strong motive to perpetuate and hide its illegal relationship with the CDF to protect its bottom line. Regeneron's motive to perpetuate its scheme

[11] Regeneron, 2013 Form 10-K Annual Report, at 20 (Feb. 13, 2014), https://tinyurl.com/yxrj7q54.
[12] Regeneron, 2014 Form 10-K Annual Report, at 23-24 (Feb. 12, 2015), https://tinyurl.com/y6nk2hz2.

only grew in the years following that scheme's inception. Indeed, in 2019, Eylea brought in over $4 billion for Regeneron, which it could not have done absent the scheme described above.

179. That same year, Regeneron warned investors that the company is "substantially dependent" on Eylea, and "any difficulty with the commercialization of Eylea" would lead to "a reduction in revenue" that would threaten Regeneron's ability "to sustain profitability."[13]

The United States Investigates Regeneron's Scheme and Brings Suit

180. Despite its best efforts, Regeneron could not keep its illegal relationship with the CDF a secret forever.

181. In 2014, the Department of Justice began scrutinizing the relationships between pharmaceutical companies and purportedly independent charities. This has resulted in the federal government recovering hundreds of millions of dollars in connection with schemes just like that described above.

182. For example, in 2017, the Department of Justice announced that United Therapeutics Corporation "agreed to pay $210 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking UT's pulmonary arterial hypertension drugs." Among other things, the Department of Justice found that United Therapeutics "routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug and that this data was used by UT to decide how much to donate to the foundation."[14]

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[13] Regeneron, 2019 Form 10-K Annual Report, at 27 (Feb. 7, 2020), https://tinyurl.com/y3zxyfkv.

[14] Department of Justice, *Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks* (Dec. 20, 2017), https://tinyurl.com/y7xsl95y.

183. Again, in 2018, the Department of Justice announced that Actelion Pharmaceuticals US, Inc. had agreed to pay $360 million "to resolve claims that it illegally used a foundation as a conduit to pay the copays of thousands of Medicare patients taking Actelion's pulmonary arterial hypertension drugs." The Department of Justice found that Actelion "routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug; it then used this information to decide how much to donate to the foundation and to confirm that its contributions were sufficient to cover the copays of only patients taking the Subject Drugs."[15]

184. Indeed, in 2019, the Department of Justice announced that the CDF itself had "agreed to pay $2 million . . . to resolve allegations that [it] violated the False Claims Act by enabling pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs." In particular, the Department of Justice determined that the CDF had "provided [a pharmaceutical company] with information concerning the number of [its] patients receiving money from CDF's . . . fund," which "made it possible for [the pharmaceutical company] to confirm that CDF was using [its] money primarily to cover co-pays for [its drug], even though other [competing] drugs were on the market."[16]

185. In 2017, the Department of Justice opened an investigation into the relationship between the CDF and Regeneron.

186. In recognition of the illegality of the conduct discussed above, Terifay retired from Regeneron very shortly after the Department of Justice began its investigation.

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[15] Department of Justice, *Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks* (Dec. 6, 2018), https://tinyurl.com/y67zsuj9.
[16] Department of Justice, Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Oct. 25, 2019), https://tinyurl.com/y4hjrb7x.

187. Over the following years, the Department of Justice subpoenaed documents and took sworn testimony from Regeneron personnel.

188. These efforts culminated in a lawsuit filed by the United States Attorney's Office for the District of Massachusetts against Regeneron on June 24, 2020. *See United States v. Regeneron Pharmaceuticals, Inc.*, Case No. 20-cv-11217 (D. Mass).

189. The United States' complaint includes detailed allegations and dozens of exhibits that shed light on Regeneron's covert and illegal scheme. Before the filing of this complaint, Regeneron successfully concealed its scheme from United and the public at large.

United Was Damaged by Regeneron's Scheme

190. Since 2011, United has paid out approximately $917 million for Eylea on behalf of Medicare beneficiaries enrolled in United plans, including approximately $73.7 million in 2013 and 2014 alone.

191. Given the extraordinarily high cost of Eylea, most United members were unable to pay their cost-sharing obligations for the drug.

192. On information and belief, most or all of the claims United paid for Eylea were not payable because they were tainted by Regeneron's illegal kickback scheme.

193. United is entitled to damages in the amount of all reimbursements paid where Regeneron, either directly through its copay card program, through the CDF or another third-party, paid United member cost-sharing amounts in the service of its illegal scheme.

194. Because of the secretive nature of Regeneron's arrangement with the CDF, which was not made public until June of 2020, United does not yet know the full scope of the damage caused by Regeneron's illegal and tortious conduct.

TOLLING

195. To the extent any limitations periods might apply to claims United has against Regeneron, those limitations periods have not run because Regeneron has engaged in continuing, repetitive, tortious conduct, causing additional and ongoing injury to United. Because Regeneron's repetitive tortious conduct has not ceased, no limitations periods on United's claims have started to run.

196. Moreover, even if one or more limitations periods could apply, they would be tolled by virtue of the discovery rule. Regeneron concealed the central components of its scheme, making it difficult to discover. Indeed, the very purpose of Regeneron using the CDF as a conduit through which to pay the cost-sharing obligations of patients taking Eylea was to conceal Regeneron's unlawful kickbacks. United only learned of this conduct on or about June 24, 2020 when the Department of Justice filed suit against Regeneron.

COUNT I: FRAUDULENT CONCEALMENT AND FRAUD

197. United incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

198. Regeneron knew that United ultimately paid for Eylea. As Regeneron has explained in SEC filings, "[s]ales in the United States of [Regeneron's] marketed products are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid."[17]

[17] Regeneron, 2019 Form 10-K Annual Report, at 24 (Feb. 7, 2020), https://tinyurl.com/y3zxyfkv.

199. Moreover, as discussed above, Regeneron monitored and facilitated United's payment of claims for Eylea through the EYLEA4U program. Regeneron's agents regularly contacted United in doing so.

200. Regeneron had superior knowledge of facts unavailable to United that Regeneron knew to be material to United's decision to reimburse for Eylea. Specifically, Regeneron had knowledge of the following facts:

a. Regeneron illegally received information from the CDF regarding the amounts needed to cover the cost-sharing obligations of Eylea patients, to the exclusion of patients using competing drugs;

b. Regeneron illegally used this information to calibrate its "donations" to the CDF to cover only the cost-sharing obligations of Eylea patients;

c. Regeneron and the CDF illegally coordinated to ensure that Regeneron's donations were ultimately routed to Eylea patients, and that the CDF's outlay on Eylea would have a one-to-one correlation with Regeneron's "donations" on at least an annual basis;

d. As a result, the CDF was not acting as an independent, *bona fide* charity, but rather as an illegal conduit for Regeneron to systematically eliminate the cost-sharing obligations of Eylea patients enrolled in United's Medicare plans;

e. The effect of Regeneron's scheme was effectively Regeneron's covert waiver of the cost-sharing obligations of most or all Eylea patients;

f. By eliminating virtually all of the cost-sharing obligations of Eylea patients through its unlawful relationship with the CDF, Regeneron was able to vastly inflate the price of Eylea;

g. Regeneron deliberately used its illegal kickback arrangement with the CDF to induce physicians to prescribe Eylea, and patients to use it; and

h. In the absence of this illegal arrangement, either Eylea patients would instead have received treatment using the much-cheaper Avastin, or Regeneron would have been forced to substantially lower the price of Eylea in order to compete with Avastin.

201. United was unaware of any of the foregoing facts.

202. The foregoing facts were material to United's decision to reimburse claims for Eylea under its Medicare plans. Indeed, the above-described facts rendered claims for Eylea submitted to United's Medicare plans not payable under federal law. Had United understood any of the foregoing, it would have refused to reimburse claims for Eylea tainted by Regeneron's unlawful scheme under its Medicare plans.

203. Regeneron knew that United lacked knowledge of the above facts, and that United would not reimburse for Eylea if it learned any of the above facts.

204. Regeneron further understood that providers submitting claims to United's Medicare plans for Eylea, whose patients had received funds Regeneron illegally funneled through the CDF, would certify that the claims were not tainted by illegal kickbacks.

205. Regeneron knew that its relationship with the CDF violated the federal Anti-Kickback Statute, rendering those certifications false.

206. Regeneron further knew that United lacked knowledge of the falsity of these certifications, and that United would rely on them in reimbursing for Eylea.

207. Regeneron's superior knowledge related to United's reimbursements for Eylea, which payments Regeneron closely monitored and facilitated, and upon which Regeneron's

business depended, gave rise to a duty on Regeneron's part to disclose the facts discussed above. Regeneron's active concealment of its illegal conduct with the intent to deceive United also independently gave rise to a duty to disclose the facts discussed above.

208. Regeneron did not disclose any of the foregoing material facts.

209. Despite regularly contacting United to monitor and facilitate payment of Eylea claims, Regeneron withheld the above facts in order to deceive United into paying Eylea claims tainted by kickbacks under its Medicare plans.

210. Indeed, rather than disclose these facts, Regeneron took active steps to hide them.

211. Regeneron knew that by concealing its scheme described above, it would deceive United into reimbursing claims for Eylea that United would not otherwise pay.

212. United reasonably believed that Regeneron and the CDF were not engaged in an illegal kickback scheme, and that the claims it received for Eylea to its Medicare plans were not tainted by illegal kickbacks.

213. United reasonably relied on those beliefs, which Regeneron deliberately fostered, in paying claims for Eylea from its Medicare plans.

214. As a result of Regeneron's fraudulent concealment, United was damaged by paying hundreds of millions of dollars—if not more—on claims for Eylea treatment that should not have been paid under its Medicare plans.

215. In addition to the above, Regeneron affirmatively misrepresented its relationship with the CDF through websites and Eylea promotional materials.

216. Among other things, Regeneron falsely represented that CDF was "an independent co-pay assistance foundation," and that "Regeneron does not influence or control the operations of patient assistance programs through independent charitable foundations."

217. Regeneron made numerous other similar public misrepresentations to this effect.

218. Regeneron understood these representations to be false, and as discussed above, actively worked to conceal the statements' falsity.

219. Regeneron intended these misrepresentations to deceive payors (including United), physicians, and patients as to the nature of Regeneron's relationship with the CDF.

220. Regeneron understood that if payors (including United) learned the true nature of Regeneron's relationship with the CDF, they would not reimburse for Eylea claims from their Medicare plans.

221. Regeneron intended that United and other administrators of Medicare Part C plans would rely on these false statements when making reimbursements.

222. United justifiably relied on Regeneron's public misrepresentations as to the nature of its relationship with the CDF.

223. Regeneron directly and proximately caused significant damages to United in the form of payments United made for Eyelea from its Medicare plans, subsequent to and because of Regeneron's false representations.

224. On information and belief, the illegal kickback scheme between Regeneron and the CDF tainted all or most of the claims submitted to United's Medicare plans for Eylea from 2013 to the present day.

225. By virtue of the foregoing, United is entitled to compensatory and punitive damages that it suffered because of Regeneron's conduct in an amount to be determined at trial.

COUNT II: TORTIOUS INTERFERENCE WITH CONTRACT

226. United incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

227. United members are each parties to United benefit plans, which are contracts between the members and United.

228. As is described in detail above, United's benefit plans, including its Medicare Part C plans, require United *members*—not others paying on their behalf—to pay the cost-sharing obligations set forth in the plans when obtaining prescription drugs, including Eylea.

229. United's Medicare Part C plans state, for example, that "as a plan member, *you* are responsible" for making coinsurance payments and that "for most of your medical services or drugs covered by the plan, *you* must pay your share of the cost when you get the service or drug." Ex. A at 206 (emphasis added).

230. Regeneron knew that United members were parties to United's Medicare Part C benefit plans and that the plans required the members to pay cost-sharing obligations. Such requirements are standard features of Medicare insurance plans, which stand as barriers between Regeneron and its goals of maintaining and increasing the prices and utilization of Eylea.

231. Moreover, Regeneron regularly contacted United and other insurers to ascertain the "cost responsibility" of specific patients for Eylea under the EYLEA4U program. Ex. AI at 2. In many cases, Regeneron had specific knowledge of the member cost-sharing obligations it subverted through its scheme.

232. Despite that knowledge, Regeneron intentionally interfered with those plan requirements by paying for and eliminating United members' cost-sharing obligations, in a deliberate effort to subvert the benefit United anticipated from those contractual provisions, by using the CDF as a conduit to make the payments and conceal itself as the source of the funds.

233. The CDF paid these funds directly to providers, meaning that United's members never made any coinsurance payment themselves, as they were required to do under the terms of their contracts.

234. Regeneron's interference caused United members to breach their agreements with United when they failed to pay the cost-sharing obligations set forth in their insurance plans.

235. Regeneron's interference and procurement of those contractual breaches was wrongful and without justification, and intended to defeat the structure of United's managed care system and to benefit Regeneron financially at United's expense.

236. The contractual breaches Regeneron caused have directly and proximately caused significant damages to United in the form of payments United made for Eyelea, subsequent to and because of those breaches, which were not due and would not otherwise have been made.

237. By virtue of the foregoing, United is entitled to compensatory and punitive damages, interest and costs, an injunction prohibiting Regeneron from continuing to engage in the tortious conduct described above, and any other relief deemed just and proper.

COUNT III: AIDING AND ABETTING TORTIOUS CONDUCT

238. United incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

239. To the extent Regeneron did not directly implement the scheme described above, it provided substantial aid and encouragement to the CDF, which also committed torts against United by interfering with United's contractual agreements with its members and fraudulently concealing Regeneron's scheme.

240. As is described in detail above, United's benefit plans require United members to pay the cost-sharing obligations set forth in the plans when obtaining prescription drugs, including Eylea.

241. The CDF knew that United members were parties to United benefit plans and that the plans required the members to pay cost-sharing obligations.

242. Even so, the CDF intentionally interfered with those plan requirements by using the funds that it obtained from Regeneron to eliminate United members' cost-sharing obligations, by paying those cost-sharing obligations directly to the billing provider.

243. The CDF's interference caused United members to breach their agreements with United when they failed to pay the cost-sharing obligations set forth in their insurance plans.

244. The CDF's interference and procurement of those contractual breaches was wrongful and without justification, conducted solely to defeat the structure of United's managed care system and to benefit Regeneron financially at United's expense.

245. For its part, Regeneron was aware of the CDF's tortious conduct, and encouraged it in the manner set forth in the Complaint.

246. Regeneron also provided substantial assistance in the achievement of the CDF's tortious interference with United members' contracts because it funded the payments that the CDF made to the providers to cover United members' cost-sharing responsibilities.

247. Regeneron's wrongful assistance to the CDF was a substantial factor in causing harm to United.

248. By virtue of the foregoing, United is entitled to compensatory and punitive damages, interest and costs, an injunction prohibiting Regeneron from continuing to engage in the tortious conduct described above, and any other relief deemed just and proper.

COUNT IV: VIOLATION OF CIVIL RICO, 18 U.S.C. § 1962(c)

249. United incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

250. Regeneron is a "person" within the meaning of 18 U.S.C. § 1961(3), which conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

251. Regeneron, the CDF, and the Lash Group entered into an association-in-fact enterprise (the "Enterprise") within the meaning of 18 U.S.C. § 1961(4). The Enterprise was an ongoing organization that functioned as a continuing unit. The Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Regeneron, the CDF and the Lash Group are each "persons" distinct from the Enterprise.

252. Regeneron established the Enterprise to inflate prices for Eylea, and to increase its sales of Eylea, by illegally using the CDF to funnel money to physicians, and to deceive insurers like United into reimbursing claims for Eylea tainted by these kickbacks by means of fraud perpetrated over the wires or by mail.

253. Each participant in the Enterprise, and Regeneron specifically, knew this scheme violated federal and state laws as discussed throughout this Complaint.

254. The Enterprise engaged in and affected interstate commerce because, among other things, it marketed and induced prescriptions for Eylea to thousands of individuals throughout the United States, illegally subsidized these Eylea sales, and facilitated payments from United and other insurers for these Eylea sales.

255. Regeneron asserted control over the Enterprise by organizing and funding the sham charitable funds that the CDF used to pay cost-sharing obligations of Medicare beneficiaries

enrolled in Medicare plans administered by United, and by establishing the EYLEA4U program to further the Enterprise's scheme.

256. Regeneron has conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to conduct unlawful activity).

257. Predicate acts of racketeering that Regeneron engaged in include, but are not limited to, causing false certifications and claims to be transmitted through the wires to United in order to fraudulently induce United to reimburse for Eylea; use of the wires to transmit and publicize false claims that Regeneron did not influence or control CDF funding in order to fraudulently induce United and other insurers to reimburse claims for Eylea; and use of the wires and mails to fraudulently conceal the Enterprise in order to induce United and other insurers to reimburse claims for Eylea.

258. Regeneron's Enterprise employed the wires and mails in furtherance of its fraudulent scheme in doing at least the following:

a. Coordinating Regeneron's illegal payments to the CDF, including by means of the communications specifically described herein;

b. Transferring illegal payments from Regeneron to the CDF, and from the CDF to prescribing physicians;

c. Using the EYLEA4U program to facilitate payments from United and other insurers, as described herein, for Eylea claims tainted by illegal kickbacks;

d. Disseminating false and misleading information to physicians, patients, and the general public (including United) concerning the

availability of purportedly "charitable" funding and the nature of Regeneron's relationship with the CDF;

e. Causing physicians to transmit false certifications that claims for Eylea complied with federal and state law; and

f. Inducing United to use the wires to pay claims tainted by the Enterprise's illegal kickback scheme.

259. The above-described acts reveals a continuous pattern of racketeering activity, in addition to the threat of continued racketeering activity.

260. The effect of Regeneron's racketeering activity was to fraudulently cause United and other insurers to reimburse claims for Eylea that they would not otherwise pay, and to maintain or raise the price of Eylea to higher levels than it would have commanded in the absence of the illegal conduct.

261. United suffered injuries when it reimbursed those prescriptions for Eylea that otherwise would not have been made and/or paid the higher prices that resulted from the illegal conduct.

262. United's injuries were directly and proximately caused by Regeneron's racketeering activities as described above.

263. By virtue of these violations of 18 U.S.C. § 1962(c), Regeneron is jointly and severally liable to United for three times the damages United has sustained in an amount to be determined at trial, plus the cost of this suit, including reasonable attorneys' fees.

COUNT V: CONSPIRACY TO VIOLATE CIVIL RICO, 18 U.S.C. § 1962(d)

264. United incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

265. 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

266. Regeneron has violated 18 U.S.C. § 1962(d) by conspiring with the CDF and the Lash Group to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Enterprise described herein through a pattern of racketeering activity.

267. Regeneron and its co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy.

268. The nature of the above-described co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but also that they were aware that their ongoing acts have been and are part of an overall pattern of racketeering activity.

269. As a direct and proximate result of Regeneron's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), United has been injured in its business and property as set forth more fully above.

270. The purpose and effect of the conspiracy was to cause United and other insurers to reimburse Eylea claims through fraud, and to maintain or raise the price of Eylea to a higher level than it would have commanded in the absence of the illegal conduct.

271. United suffered injuries when it paid the higher prices that resulted from the illegal, conspiratorial conduct.

272. By virtue of these violations of 18 U.S.C. § 1962(d), Regeneron is jointly and severally liable to United for three times the damages United has sustained in an amount to be determined at trial, plus the cost of this suit, including reasonable attorneys' fees.

COUNT VI: UNJUST ENRICHMENT

273. United incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

274. United has conferred direct benefits on Regeneron in the form of significant payments based on claims for Eylea utilized by United members, and Regeneron has knowledge of those benefits.

275. Regeneron has voluntarily accepted and retained the payments it has received and other associated benefits conveyed to it by United as a result of its scheme to pay United member cost-sharing obligations.

276. Under the circumstances of this case, it would be inequitable for Regeneron to retain the payments and benefits it has received at United's expense.

277. The money Regeneron has received from United belongs in equity and good conscience to United.

278. By virtue of the foregoing, United is entitled to recover the substantial amount of payments Regeneron has improperly retained.

COUNT VII: Violation of New York General Business Law § 349 and Other State Deceptive Trade Practices Laws

279. United incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

280. United is a person or consumer entitled to protection under New York's and other states' consumer protection laws.

281. By concealing its coordination and cooperation with the CDF to pay for and eliminate United member's cost-sharing obligations, Regeneron deceived United into paying reimbursements for claims made by its New York based members that it otherwise would not have paid.

282. Regeneron's conduct affected not only United, but also other similarly-situated payors, as evidenced by the False Claims Act case filed by the United States Government against Regeneron.

283. Regeneron directly and proximately caused significant damages to United in the form of payments United made for Eylea, because of Regeneron's deception.

284. In addition to New York's General Business law § 349, Regeneron's nationwide fraudulent and deceptive business practices described herein violated the state consumer fraud, consumer protection, and/or deceptive trade practices laws of other states, and in particular the following laws:

a. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.* (Arizona);

b. Cal. Bus. & Prof. Code § 17200, *et seq.* (California);

c. Colo. Rev. Stat. § 6-1-101, *et seq.* (Colorado);

d. Fla. Stat. § 501.201, *et seq.* (Florida);

e. 815 Ill. Comp. Stat. 505/1, *et seq.* (Illinois);

f. Mich. Comp. Laws § 445.901, *et seq.* (Michigan);

g. Minn. Stat. § 325F.68, *et seq.* (Minnesota);

h. Neb. Rev. Stat. § 59-1601, *et seq.* (Nebraska);

i. Nev. Rev. Stat. § 41.600, *et seq.* (Nevada);

j. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.* (New Hampshire);

k. N.C. Gen. Stat. § 75-1.1, *et seq.* (North Carolina);

285. Regeneron's conduct offends established public policy and the public interest, and is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

286. United is therefore entitled to actual damages or damages for each deception that occurred, punitive damages, and attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, United respectfully requests an award in its favor and granting the following relief:

a. An award of compensatory damages as requested herein;

b. Equitable relief as requested herein;

c. Injunctive relief as requested herein;

d. Treble damages under 18 U.S.C. § 1964(c);

e. Costs of court;

f. Reasonable attorney fees;

g. Prejudgment and post-judgment interest; and

h. An award of any other relief in law or equity that the Court deems just and proper.

Dated: December 17, 2020

By: *s/ Ronald J. Schutz*

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